DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 3, 2015

Ivoclar Vivadent, Inc.
Ms. Donna Marie Hartnett, Esq.
Director, QA/Regulatory Affairs
175 Pineview Drive
Amherst, NY 14228

Re: K150164
Trade/Device Name: Monobond® Etch & Prime
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE
Dated: January 21, 2015
Received: January 26, 2015

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150164

Device Name
MONOBOND ETCH & PRIME

Indications for Use *(Describe)*
Conditioning of silica-based ceramic surfaces for the adhesive bond with luting composites

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY (rev 2.10.15)
## Monobond® Etch & Prime

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan
FL-9494, Liechtenstein
+423-235-3535

Date Prepared: February 10, 2015

Proprietary Name: **Monobond® Etch & Prime**

Classification Name: Agent, Tooth bonding, Resin (872.3200)
(Classification Code KLE)

**Predicate Device:** Monobond Plus (K090826)

**Device Description:** Monobond Etch & Prime is used to condition silica-based ceramic surfaces for the adhesive bond with luting composites from the Variolink or Multilink product lines, for example. Monobond Etch & Prime etches and silanizes silicate ceramic surfaces in one working step. The new product combines the role of bonding agent with that of etchant. Typically the dental technician would etch the ceramic with 5% hydrofluoric acid but this step is achieved using Monobond Etch & Prime. The etching step was carried out outside the mouth and the new product is also limited to extra-oral application. The indications of the new product are limited to silica ceramics. Oxide ceramics, metal, composite and fibre-reinforced composites are not indicated. This is because only silica glass ceramics required etching with hydrofluoric acid and therefore the benefit of using Monobond Etch & Prime is primarily relevant for this group of materials.

### Intended Use:

Conditioning of silica-based ceramic surfaces for the adhesive bond with luting composites

**Comparison to Predicate:** The predicate device to which Monobond Etch & Prime has been compared is Monobond Plus (K090826). For this application, Monobond Etch & Prime has been compared to its predicate with regard to chemical composition, physical properties, and indications for use. The comparison shows that Monobond Etch & Prime is substantially equivalent to the predicate device.

| Predicate - Monobond Plus (K090826) | Subject Device |
|---|---|
| Bonding agent between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations. | Conditioning of silica-based ceramic surfaces for the adhesive bond with luting composites. |
| Monobond Plus is a dilute solution of adhesive monomers and silane which enable it to be used with various substrates. | Monobond Etch & Prime is a dilute solution of silane, a ceramic etching agent and an adhesive monomer, and can be used only with silica ceramics |
| Tensile bond strength to glass ceramics was tested for comparison purposes to the subject device. | Tensile bond strength testing showed that the performance of the subject device is conforming to the specification and substantially equivalent to the predicate device. |

**Technological Characteristics and Testing Summary**: As no product specific standard exists for the subject device, testing was conducted under ISO 1641:2009 Dentistry – Medical Devices for dentistry – Materials.

The device was tested for Tensile bond strength. The predicate referred to shear bond strength. The methods and specifications cannot be directly compared. However, tests for Monobond Etch & Prime and Monobond Plus tensile bond strength showed that the performance of the new product is conforming to the specification and substantially equivalent to the predicate. Only the bond strength to glass ceramics is considered as use with oxide ceramics is not indicated for Monobond Etch & Prime. The key function of Monobond Etch & Prime is to silanise silica glass ceramics. This is achieved using exactly the same silane agent as used in Monobond Plus. Although the compositions are different, the subject device has been assessed for biocompatibility through testing according EN ISO 10993-1:2009 and EN ISO 7405:2008.

The device design, i.e. delivery form, and the predicate device are the same. They are both applied extra-orally. The Intended use of the subject and the predicate device are the same except that the subject device is limited for use with silica-based ceramic surfaces. This be because only silica glass ceramics require etching with hydrofluoric acid and therefore the benefit of using the subject device is relevant for this group of materials.

**CONCLUSION**: The above data and analysis demonstrates that Monobond Etch & Prime is substantially equivalent to the predicate device.